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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/653,879 | 09/02/2003 | Timothy B. Petrick | 891,144-001 | 5033 |

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| EXAMINER | |
|---|---|
| CAMPBELL, VICTORIA P | |

| ART UNIT | PAPER NUMBER |
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| 4123 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/653,879 | PETRICK ET AL. | |
| | Examiner | Art Unit | |
| | VICTORIA P. CAMPBELL | 4123 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14,23,31,40,48,57,63 and 72-78* is/are pending in the application.

4a) Of the above claim(s) *1-14,31,40,48,57 and 63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 72-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2/03, 10/13/05, 6/12/06, 10/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group I and Species C as defined by the examiner in the reply filed on December 18, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

This is the initial Office Action based on the 10/653879 application filed September 2, 2003. Claims 23 and 72-78 as elected are currently pending and considered below.

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: #51 in Figure 1, #80 in Figure 7A, and #90' shown in Figures 7C, 7E, and 7F. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37

CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Specification*

2. The abstract of the disclosure is objected to because the first statement is not a complete sentence. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities:

Page 2, line 11 reads "may perforate vessel" but should read --may perforate the vessel--.

Appropriate correction is required.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 23, 72-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over US PGPub 2001/0021831 A1 to Fleischhacker et al in view of US PGPub 2002/0077595 A1 to Hundertmark et al.

Regarding the instant claims, Fleischhacker et al teach the following:

**23.** A catheter, comprising: an elongate tubular member having a proximal region, a distal region, and a lumen extending therebetween (Fig. 24, #100); a multilayer torque cable in the proximal region of the elongate tubular member, the multilayer torque cable having a first helical coil (Fig. 24, M) and a second

helical coil (Fig. 24, N), the first helical coil nested within the second helical coil and wound in a reverse direction from the second helical coil (see Fig. 12) so that rotation of the first helical coil in a first direction causes the first helical coil to expand while rotation of the second helical coil in the first direction causes the second helical coil to compress and thereby interfere with the expansion of the first helical coil (this behavior is inherent to the coils) [...].

**72.** [...] wherein the multilayer torque cable further comprises a third helical coil surrounding the second helical coil (Fig. 31, O).

**74.** [...] wherein the first helical coil is multifilar (Abstract).

**75.** [...] wherein the second helical coil is multifilar (Abstract).

**76.** [...] wherein the monolayer helical coil is multifilar (Abstract).

Fleischhacker et al do not teach or disclose a monolayer helical coil in the distal region of the elongate tubular member or an outer jacket surrounding the monolayer helical coil. However, regarding the instant claims, Hundertmark et al teach:

**23.** [...] a monolayer helical coil (Fig. 8, #48) in the distal region of the elongate tubular member (Fig. 2, #22); and an outer jacket surrounding the monolayer helical coil (Fig. 8, #50) to restrict expansion on rotation of the monolayer helical coil (the outer jacket of Hundertmark et al would be capable of performing this function).

**73.** [...] wherein the monolayer helical coil is annealed to prevent unwinding expansion on torquing the catheter (Paragraph [0030]).

Fleischhacker et al and Hundertmark et al are analogous art because they are from the same field of endeavor/problem solving area of helically wound catheters. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Fleischhacker et al and Hundertmark et al before him or her to modify the multilayer catheter of Fleischhacker et al to include the monolayer distal coil of Hundertmark et al because it provides a more flexible and atraumatic end (Hundertmark et al, Abstract). Therefore, it would have been obvious to combine Fleischhacker et al with Hundertmark et al to obtain the invention in the instant claims.

9. Claims 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over US PGPub 2001/0021831 A1 to Fleischhacker et al in view of US PGPub 2002/0077595 A1 to Hundertmark et al in further view of US PGPub 2003/0105426 A1 to Jorgensen.

Regarding claims 77 and 78, Fleischhacker et al and Hundertmark et al teach the limitations of claim 23 as mentioned above. Additionally, Fleischhacker et al teach the following:

**78.** wherein a second outer jacket is disposed about the multilayer torque cable (Fig. 24, #108)

Fleischhacker et al and Hundertmark et al fail to explicitly teach or disclose a balloon mounted on the distal region of the elongate tubular member, attached to the outer jackets surrounding the monolayer helical coil and multilayer torque cable. Jorgensen teaches:

**77.** [...] further comprising a balloon (Fig. 2A, #46) mounted on the distal region of the elongate tubular member, the balloon defining a chamber (Fig. 2A, not labeled) that communicates with an inflation lumen (Fig. 2A, #52) that extends to the proximal region of the elongate tubular member (Fig. 2A, #43).

**78.** [...] wherein a proximal end of the balloon is bonded to the second outer jacket (Fig. 2A, #46, 47, and 42) and a distal end of the balloon is bonded to the outer jacket surrounding the monolayer helical coil (Fig. 2A, #46, 53, and 44).

Fleischhacker et al, Hundertmark et al and Jorgensen are analogous art because they are from the same field of endeavor/problem solving area of catheters. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Fleischhacker et al, Hundertmark et al, and Jorgensen before him or her to modify the distal end of the catheter of Fleischhacker et al and Hundertmark et al to include the balloon of Jorgensen because the device would then be useful to perform balloon angioplasty or stenting (Jorgensen, Paragraph [0002]). Therefore, it would have been obvious to combine Jorgensen with Fleischhacker et al and Hundertmark et al to obtain the invention in the instant claims.

## ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPN 5,358,493 to Schweich, Jr. et al also had a distal monolayer helical coil.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VPC

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4123